



Page 1615

Docket No. ORT-1448

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : QIN et al

Serial No. : 09/875,456

Art Unit:

Filed : June 6, 2001

Examiner:

For : THE HUMAN VOLTAGE GATED SODIUM CHANNEL B1A SUBUNIT  
AND METHOD OF USE

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Myra H. McCormack

(Name of applicant, assignee, or Registered Representative)

*Myra H. McCormack*

(Signature)

February 12, 2002

(Date of Signature)

Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37  
C.F.R. §§1.97-1.98, information relating to the above-identified  
application is hereby disclosed. Inclusion of information in  
this statement is not to be construed as an admission that this  
information is material as that term is defined in 37 C.F.R.  
§1.56(b).

Applicant(s) reserve(s) the right to establish the  
patentability of the claimed invention over any of the  
information provided herewith, and/or to prove that this  
information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached);  
or

☐ Please charge Deposit Account No. 10-0750/ /  
the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached);  
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☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ There are no listed references which are not in the English language.


☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

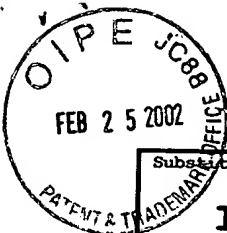
☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1448/MHM. This form is submitted in triplicate.

Respectfully submitted,

  
Myra H. McCormack  
Reg. NO. 36602  
Attorney for Applicants

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DATED: February 12, 2002



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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 4

Application Number	09/875,456
Filing Date	June 6, 2001
First Named Inventor	Qin, et al.
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	ORT-1448

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
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## FOREIGN PATENT DOCUMENTS

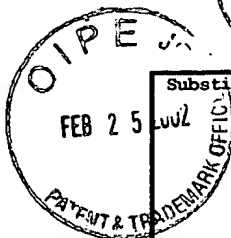
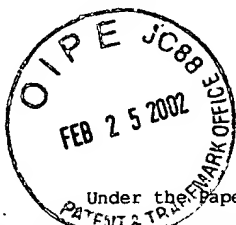
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1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Application Number	09/875,456
Filing Date	June 6, 2001
First Named Inventor	Qin, et al.
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	ORT-1448

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials *	Citation No. 1	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
2	1	BALSER, JEFFREY R, "Structure And Function Of The Cardiac Sodium Channels," Cardiovascular Research (1999) 42:327-338	1
2	2	CATTERALL, William A., "Cellular And Molecular Biology Of Voltage-Gated Sodium Channels," Pharmaceutical Rev. (1992) 72 (4) S15-S48	1
2	3	CATTERALL, William A., "Structure And Function Of Voltage-Gated Ion Channels", Trends Neurosci (1993) 16:500-506	1
2	4	CHABAL, Charles, Et Al., "The Effect Of Intravenous Lidocaine, Tocainide, And Mexiletine On Spontaneously Active Fibers Originating In Rat Sciatic Neuromas, Pain," (1989) 38:333-338	1
2	5	CHAPLAN, S.R., et al., "QUANTITATIVE ASSESSMENT OF TACTILE ALLODYNIA IN THE RAT PAW," JOURNAL OF NEUROSCIENCE METHODS (1994) 53:55-63	1
2	6	D'ANDREA, MICHAEL R., et al., "CHARACTERIZATION OF PROTEASE-ACTIVATED RECEPTOR-2 IMMUNOREACTIVITY IN NORMAL HUMAN TISSUES," JOURNAL OF HISTOCHEMISTRY & CYTOCHEMISTRY, (1998) VOL. 46(2): 157-164	1
2	7	DEVOR, MARSHALL et. al., "NA <sup>+</sup> CHANNEL ACCUMULATION ON AXOLEMMA OF AFFERENT ENDINGS IN NERVE END NEUROMAS IN APTERONOTUS," NEUROSCIENCE LETTERS, 102 (1989) 149-154	1
2	8	DEVOR, MARSHALL, "THE PATHOPHYSIOLOGY OF DAMAGED PERIPHERAL NERVES, IN TEXTBOOK OF PAIN," eds Wall PD, Melzack R., (Churchill Livingstone, Edinburgh) 2nd ED, (1994) pp.79-101	1
2	9	DEVOR, MARSHALL, et al., "SYSTEMIC LIDOCAINE SILENCES ECTOPIC NEUROMA AND DRG DISCHARGE WITHOUT BLOCKING NERVE CONDUCTION, PAIN," (1992) 48:261-268	1
2	10	DIB-HAJJ, et al. "Down-Regulation of Transcripts for Na Channel $\alpha$ -SNS IN SPINAL SENSORY NEURONS FOLLOWING AXOTOMY," Proc. Natl acad. Sci. (USA) (1996) Vol. 93:14950-14954.	1
2	11	ECKER, DAVID J., et al., "Increasing Gene Expression In Yeast By Fusion To Ubiquitin," Journal of Biological Chemistry (1989) Vol. 264, 7715-7719	1
2	12	ENGLAND JD, et al, "Sodium channels accumulate at the tips of injured axons." Muscle Nerve (1994) 17:593-598.	1
2	13	ENGLAND, J.D., et al. "Sodium Channel Accumulation In Humans With Painful Neuromas," American Academy of Neurology, (1996) 47:272-276.	1
2	14	GOULD, HARRY J. III, et al., "Rapid Sodium Channel Augmentation In Response To Inflammation Induced By Complete Freund's Adjuvant," Brain Research (1998) 802:69-74	1
2	15	HOROWITZ, et al, "Synthesis And Assembly Of Functional Mammalian Na,K-ATPase In Yeast," Journal of Biological Chemistry (1990) 265:4189-4192	1
2	16	ISOM, L.L., et al. "Primary Structure And Functional Expression Of The $\beta_1$ Subunit Of The Rat Brain Sodium Channel," Science (1992) Vol. 256:839-842	1
2	17	ISOM, L.L., et al. "Structure And Function Of The $\beta_2$ Subunit Of Brain Sodium Channels, A Transmembrane Glycoprotein With A Cam Motif," Cell, (1995) Vol. 83:433-442	1

Examiner Signature	Date Considered
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Sheet 3 of 4

Application Number	09/875,456
Filing Date	June 6, 2001
First Named Inventor	Qin, et al.
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Attorney Docket Number	ORT-1448

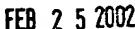
2	18	ISOM, L.L., et al. "AUXILIARY SUBUNITS OF VOLTAGE-GATED ION CHANNELS," Neuron, (1994), Vol 12 1183-1194	/
2	19	JACOBSON, et al., "Expression And Secretion Of Biologically Active Echistatin In Saccharomyces Cerevisiae," Gene (1989) 85:511-516	/
2	20	KITTS, PAUL A., et al., "Linearization Of Baculovirus DNA Enhances The Recovery of Recombinant Virus Expression Vectors," Nucleic Acids Research (1990), 5667-5672	/
2	21	MARBAN, et. al., "Structure And Function Of Voltage-Gated Sodium Channels," Journal of Physiology (1998), 647-657	/
2	22	MATZNER et al., "Na+ Conductance And The Threshold For Repetitive Neuronal Firing," Brain Research (1992) 92-98	/
2	23	MATZNER O, et al., "Hyperexcitability at sites of nerve injury depends on voltage-sensitive Na+ channels," J. Neurophysiol. (1994) 72:349-359.	/
2	24	MCDONNELL, D. et al., "RECONSTRUCTION OF THE VITAMIN D-RESPONSIVE OSTEOCALCIN TRANSCRIPTION UNIT IN SACCHAROMYCES CEREVISIAE," Molecular & Cellular Biology, Vol.9 No. 8: 3517-3523 (1989)	/
2	25	NORDIN, et al., "ECTOPIC SENSORY DISCHARGES AND PARESTHESIAE IN PATIENTS WITH DISORDERS OF PERIPHERAL NERVES, DORSAL ROOTS AND DORSAL COLUMNS," Pain 20 (1984), 231-245	/
2	26	OCHOA, et al., "PARAESTHESIAE FROM ECTOPIC IMPULSE GENERATION IN HUMAN SENSORY NERVES," Brain (1980) 103, 835-853	/
2	27	OH, YOUNGSUK, et al., "Na+ Channel $\beta 1$ SUBUNIT mRNA; DIFFERENTIAL EXPRESSION IN RAT SPINAL SENSORY NEURONS," Molecular Brain Research, 30 (1995) 357-361	/
2	28	OMANA-ZAPATA, IMELDA, et al., "Tetrodotoxin Inhibits Neuropathic Ectopic Activity In Neuromas, Dorsal Root Ganglia And Dorsal Horn Neurons," Pain 72 (1997) 41-49	/
2	29	PORRECA, FRANK, et al., "A Comparison Of The Potential Role Of The Tetrodotoxin-Insensitive Sodium Channels, Pn3/Sns And Nan/Sns2, In Rat Models Of Chronic Pain," Proc. Natl. Acad. Sci., USA, Vol. 96 (1999) 7640-7644	/
2	30	RIEHL-BELLON, NADINE et al., "Purification And Biochemical Characterization Of Recombinant Hirudin Produced By Saccharomyces Cerevisiae," Biochemistry 28 (1989) 2941-2949	/
2	31	RINAS, URSULA, et al., "CHARACTERIZATION OF RECOMBINANT FACTOR XiiiA PRODUCED IN SACCHAROMYCES CEREVISIAE," Biotechnology June (1990), 543-546	/
2	32	RIZZO, MARCO A., "Successful Treatment Of Painful Traumatic Mononeuropathy With Carbamazepine; Insights Into A Possible Molecular Pain Mechanism," Journal of Neurological Sciences, 152 (1997) 103-106	/
2	33	SABIN, E. et al., "High-Level Expression And In Vivo Processing Of Chimeric Ubiquitin Fusion Proteins In Saccharomyces Cerevisiae," Biotechnology (1989) Vol. 7: 705-709	/
2	34	SLEEP, D. et al., "The Secretion Of Human Serum Albumin From The Yeast Saccharomyces Cerevisiae Using Five Different Leader Sequences," Biotechnology, (1990) Vol., 8:42-45	/
2	35	SUTKOWSKI et al., " $\beta 1$ Subunits Of Sodium Channels," The Journal of Biological Chemistry 265 (1990)12393-12399	/
2	36	TANAKA, M., et al., "Sns Na+ Channel Expression Increases In Dorsal Root Ganglion Neurons In The Carrageenan Inflammatory Pain Model," Molecular Neuroscience, (1998) Vol. 9:967-972	/

Examiner Signature	<i>Jan</i>	Date Considered	3-31-03
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<b>Filing Date</b>	June 6, 2009
<b>First Named Inventor</b>	Qin, et. al.
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	ORT-1448

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## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Signature	<i>John - [unclear]</i>	Date Considered	3-31-01
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